

# SPECIFICATION

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## **METHOD AND DISPOSABLE APPARATUS FOR GUIDING NEEDLES WITH AN ENDOCAVITY MEDICAL IMAGING DEVICE**

### Cross Reference to Related Applications

This is a continuation-in-part application of application number 10/065,442 entitled "METHOD AND DISPOSABLE APPARATUS FOR GUIDING NEEDLES WITH AN ENDOCAVITY MEDICAL IMAGING DEVICE," filed on October 17, 2002, which application relates to co-pending application entitled "METHOD AND DISPOSABLE APPARATUS FOR GUIDING NEEDLES", application number 10/065,029, filed on September 11, 2002, by Rick L. Pruter and Quannah Lee Bain.

### Background of Invention

- [0001] In recent years, handheld medical imaging transceivers, such as ultrasound and gamma ray transceivers, have been used extensively for various medical imaging situations.
- [0002] In the past, the physician or medical professional typically will cover an ultrasound transceiver with a sterile sheath. Usually, under the sheath is a mounting bracket attached to the transceiver. A needle guide is then typically attached over the sheath and coupled to the underlying bracket. The sheath protects the transceiver and bracket.
- [0003] While these needle guides have been used extensively in the past, they do have some drawbacks. First of all, these needle guides are not covered by the sheath and consequently, must be sterilized after each use or discarded. In the past, these needle

guides have been substantial in size and in cost. The substantial nature of the needle guide can often result in the medical professional deciding to retain the needle guide and sterilize it even if the manufacturer intended it to be disposable.

[0004] Secondly, these needle guides are often at least partially inserted into a patient's rectum or vagina. When they are rotated *in situ*, discomfort can occur from any protuberance such as a needle guide coupled to the transceiver.

[0005] Consequently, there exists a need for improved methods and apparatus for guiding needles in an efficient manner.

### Summary of Invention

[0006] It is an object of the present invention to provide an apparatus and method for guiding a needle in an efficient manner.

[0007] It is a feature of the present invention to include a non-reusable needle guide.

[0008] It is another feature of the present invention to include a needle guide, bracket and transceiver combination which is free from large protruding surface features which could cause patient discomfort, especially when rotated *in situ*.

[0009] It is another feature of the present invention to include an enlarged needle-receiving area on a needle guide to facilitate quick insertion of the needle therein.

[0010] It is another feature of the present invention to include a needle guide-to-bracket attachment mechanism which is adapted for positive attachment to the bracket with a predetermined grasping force in a non-reusable manner.

[0011] It is an advantage of the present invention to achieve improved efficiency in guiding needles.

[0012] The present invention is an apparatus and method for guiding needles, designed to satisfy the aforementioned needs, provide the previously stated objects, include the above-listed features, and achieve the already articulated advantages. The present invention is carried out in a "physician burden-less" manner in a sense that the burden on a physician or other medical professional in guiding needles during the process of insertion into the needle guide, has been greatly reduced. Additionally, the

system is carried out in a reduced discomfort manner in the sense that the patient discomfort associated with rotating a transceiver/bracket/needle guide combination *in situ* is reduced. Finally, the present invention is carried out in a disposable manner in the sense that the base and the clamp used to couple it to the sheathed bracket are designed to be used only once and then discarded.

[0013] Accordingly, the present invention is an apparatus and method including a needle guide with enlarged needle-receiving portions on the needle guide, and base-to-bracket locks which are non-reusable.

### Brief Description of Drawings

[0014] The invention may be more fully understood by reading the following description of the preferred embodiments of the invention, in conjunction with the appended drawings wherein:

[0015] Figure 1 is a perspective view of the apparatus of the present invention in conjunction with a medical imaging transceiver.

[0016] Figure 2 is an exploded perspective diagram of the apparatus of Figure 1 where the dashed lines represent lines along which the respective elements have been moved. Portions of sterilized sheath 241 are represented in a cross-sectional view.

[0017] Figure 3 is an end view of the proximal end 134 of the needle guide 130.

[0018] Figure 4 is an exploded diagram of an alternate embodiment of the present invention which shows a front clip.

[0019] Figure 5 is a cross-sectional view of the front clip of Figure 4.

[0020] Figure 6 is a cross-sectional view of the rear clip of Figure 4.

### Detailed Description

[0021]

Now referring to the drawings wherein like numerals refer to like matter throughout, and more specifically referring to Figure 1, there is shown a needle guide, bracket and medical imaging transceiver system of the present invention generally designated 100. The system 100 includes a medical imaging transceiver 110 which

could be any type of imaging system or device, and a transceiver mounting bracket 120, which is coupled to said medical imaging transceiver 110 for the purpose of facilitating coupling with needle guides and other instruments. Medical imaging transceiver 110 is preferably an endocavity transceiver. The term "endocavity" is used herein to refer to an object, apparatus, device, etc. which is sized, shaped and configured for trans-rectal and trans-vaginal use. Mounting bracket 120 can be coupled to medical imaging transceiver 110 in any suitable manner, such as clamps, screws, adhesive, etc. Transceiver/bracket covering sterile sheath (Fig. 2) is disposed about mounting bracket 120 and medical imaging transceiver 110 in a well-known manner. Needle guide assembly 130 is shown having a needle guide enlarged proximal end 134 being enlarged with respect to side clamp leg 139.

[0022] Mounting bracket 120 is preferably designed to firmly attach to medical imaging transceiver 110 and to fill in the space available about reduced cross section medical imaging transceiver middle section 116. Mounting bracket 120 includes a mounting bracket distal end 122 and a mounting bracket proximal end 124. Mounting bracket 120 preferably is a partial sleeve which is sized and configured to be placed over the reduced cross-section medical imaging transceiver middle section 116 and to firmly grasp medical imaging transceiver 110. Mounting bracket 120 may have at its mounting bracket proximal end 124 a plurality of bracket clamp legs 125. Now referring to Figure 2, the mounting bracket 120 includes a mounting bracket needle guide receiving slot 226 and a mounting bracket needle guide receiving platform 228, as well as a mounting bracket protuberance receiving void 227.

[0023] Now Referring to Figures 1, 2 and 3, there is shown a needle guide 130 of the present invention. Needle guide 130 includes a needle guide distal end 132 and a needle guide enlarged proximal end 134 and a needle guide central cannula section 136. Needle guide enlarged proximal end 134 is preferably larger than side clamp leg 139 and thereby creating a needle guide grasping depression 331, (Figure 3) into which a person's finger can rest when a force is applied to the needle guide 130 to separate it from the sheath covered mounting bracket 120. Preferably, the orientation of side clamp leg protuberance 137, side clamp leg 139 and mounting bracket protuberance receiving void 227 are such that when a lifting force is applied on needle guide enlarged proximal end 134, the side clamp leg protuberance 137 is

caused to shear off before side clamp leg 139 is spread sufficiently to allow non-destructive removal of the needle guide 130 from the sheathed mounting bracket 120. Numerous other methods of securing needle guide 130 to mounting bracket 120 exist which would necessitate destruction upon removal. For example, needle guide 130 might include a bullet-nose plastic member which locks upon insertion and is only unlocked by destruction of the bullet-nose member. Still other well-known means of attachments could be used as well.

[0024] In operation, the apparatus and method of the present invention as described and shown in Figures 1-3, could function as follows:

[0025] Mounting bracket 120 is mounted on a medical imaging transceiver 110. A transceiver/mounting bracket sterile sheath 241 is pulled over the medical imaging transceiver 110 and mounting bracket 120 combination. Needle guide 130 is pushed onto mounting bracket 120, so that side clamp leg 139 separates (see dotted lines in Fig 3) to allow further depression until side clamp leg protuberance 137 slips into mounting bracket protuberance receiving void 227, thereby firmly attaching needle guide 130 to the transceiver/mounting bracket sterile sheath 241 covered mounting bracket 120. Needle guide central cannula section 136 fits into mounting bracket needle guide receiving slot 226. When needle guide 130 is firmly attached to mounting bracket 120, the medical professional can insert a needle or other instrument into needle guide enlarged needle receiving area 138 and then into the needle guide central cannula section 136. Ultimately, the needle or other instrument is disposed beyond the mounting bracket distal end 122 and is able to enter a patient's tissue.

[0026] Now referring to Figures 4 and 5, there is shown an alternate embodiment of the present invention, which includes a medical imaging transceiver 110 and a dual clip needle guide mounting bracket 420 and a dual clip needle guide 430. Dual clip needle guide mounting bracket 420 is similar to mounting bracket 120 except for the variations required to mate with the dual clip needle guide 430 instead of the needle guide 130. Dual clip needle guide mounting bracket 420 couples to medical imaging transceiver 110 as described above with respect to mounting bracket 120. Dual clip needle guide 430 includes a dual clip needle guide front clip end 432 and a dual clip

needle guide needle inlet end 434. Dual clip needle guide needle inlet end 434 includes a dual clip needle guide funnel 438 and a dual clip needle guide bracket leg 439. Dual clip needle guide 430 also includes a dual clip needle guide front clip end 432 which is separated by the cannula 436. Dual clip needle guide front clip end 432 includes a front leg 431, which has a dual clip needle guide leg protuberance 502 disposed along its inside distal end. Dual clip needle guide leg protuberance 502 includes a dual clip needle guide leg protuberance leading edge 504, a dual clip needle guide leg protuberance insertion contact surface 506, a dual clip needle guide leg protuberance seated contact surface 508 and a dual clip needle guide leg protuberance to leg void 510.

[0027] Dual clip needle guide front clip end 432 also includes a second dual clip needle guide leg protuberance 512, a dual clip needle guide front cannula section 520 and a dual clip needle guide front flat base section 530.

[0028] Now referring to Figure 6, there is shown a cross-sectional view of dual clip needle guide needle inlet end 434, which includes a dual clip needle guide rear clip leg protuberance 602, dual clip needle guide rear leg protuberance leading edge 604, dual clip needle guide rear leg protuberance insertion contact surface 606, dual clip needle guide rear leg protuberance seated contact surface 608 and dual clip needle guide rear leg protuberance to leg void 610 and a second dual clip needle guide rear leg protuberance 612.

[0029] The alternate embodiment of Figures 4-6 operates as follows:

[0030] The dual clip needle guide 430 is pressed down onto dual clip needle guide mounting bracket 420. Dual clip needle guide leg protuberance insertion contact surface 506 and dual clip needle guide rear leg protuberance insertion contact surface 606 contact the exterior of dual clip needle guide mounting bracket 420. Dual clip needle guide bracket leg 439 and front leg 431 spread apart as dual clip needle guide 430 is pressed harder downward. When dual clip needle guide leg protuberance 502 and dual clip needle guide rear clip leg protuberance 602 reach voids in the side of dual clip needle guide mounting bracket 420, they are forced into such voids. When dual clip needle guide leg protuberance 502 and dual clip needle guide rear clip leg protuberance 602 are in the voids, they firmly hold the dual clip needle guide 430 to

the dual clip needle guide mounting bracket 420.

[0031] When the dual clip needle guide 430 is to be removed, upward pressure is applied to the dual clip needle guide needle inlet end 434 and dual clip needle guide front clip end 432. Because of the reduced thickness associated with dual clip needle guide leg protuberance to leg void 510 and dual clip needle guide rear leg protuberance to leg void 610, the dual clip needle guide leg protuberance 502 and the dual clip needle guide rear clip leg protuberance 602 respectively, are deformed beyond their elastic limits, and dual clip needle guide 430 becomes removable from the voids in dual clip needle guide mounting bracket 420. Once dual clip needle guide leg protuberance 502 and dual clip needle guide rear clip leg protuberance 602 are deformed beyond their elastic limits, they are no longer capable of causing the dual clip needle guide 430 to be firmly attached to dual clip needle guide mounting bracket 420.

[0032] Throughout this description, reference is made to a medical imaging system, because it is believed that the beneficial aspects of the present invention would be most readily apparent when used in connection with medical imaging; however, it should be understood that the present invention is not intended to be limited to imaging, and should be hereby construed to include other medical tools, equipment and methodologies as well, where it is desirable to guide a needle or other elongated medical instrument.

[0033] It is thought that the method and apparatus of the present invention will be understood from the foregoing description and that it will be apparent that various changes may be made in the form, construct steps, and arrangement of the parts and steps thereof, without departing from the spirit and scope of the invention or sacrificing all of their material advantages. The form herein described is merely a preferred exemplary embodiment thereof.